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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,492	04/08/2004	David J. Bayer	04819-15	7284
7590 12/10/2008				
John S. Beulick Armstrong Teasdale LLP Suite 2600 One Metropolitan Square St. Louis, MO 63102				
EXAMINER				
NATNITHITHADHA, NAVIN				
ART UNIT		PAPER NUMBER		
3735				
MAIL DATE		DELIVERY MODE		
12/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,492

Applicant(s)

BAYER ET AL.

Examiner

NAVIN NATNITHITHADHA

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-13, 15-16, 23-55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-13, 15, 16, 23-55 and 57-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. According to the Amendment, filed 28 August 2008, the status of the claims is as follows:

Claims 1, 36, 47, and 61 are currently amended;

Claims 5-12, 15, 16, 24, 26-35, 37-45, 48-53, 55, and 57-60 are as originally filed;

Claims 4, 13, 23, 25, 46, and 54 are previously presented; and

Claims 2, 3, 14, 17-22, and 56 are cancelled.

Response to Arguments

2. Applicant's arguments, see Remarks, pp. 12-14, filed 28 August 2008, with respect to the rejection of claims 1, 4-10, and 12 under 35 U.S.C. 103(a) as being Mault et al, U.S. Patent No. 6,468,222 B1 ("Mault"), in view of Sheehan et al, U.S. Patent No. 6,319,199 B1 ("Sheehan"), and Raemer et al, U.S. Patent No. 4,233,842 A ("Raemer"), have been fully considered, but are moot in view of the new ground(s) of rejection.

3. Applicant's arguments, see Remarks, pp. 14-15, filed 28 August 2008, with respect to the rejection of claim 11 under 35 U.S.C. 103(a) as being Mault in view of Sheehan and Raemer, as applied to claim 1 above, and further in view of Wolf, U.S. Patent No. 5,291,898 A ("Wolf"), have been fully considered, but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments, see Remarks, pp. 15-16, filed 28 August 2008, with respect to the rejection of claims 13, 15, and 16 under 35 U.S.C. 103(a) as being Lutz et al, U.S. Patent No. 4,274,425 A ("Lutz") in view of Mault, have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, p. 16, that "Neither Lutz nor Mault, considered alone or in combination, describes or suggests a mouthpiece for a breath testing device as is recited in Claim 13. More specifically, neither Lutz nor Mault, considered alone or in combination, describes nor suggests a mouthpiece that includes a discard breath outlet oriented such that discard breath is not directed into the device or at an operator of the breath testing device during testing when the operator views the display, and wherein the mouthpiece includes either a D-shaped or a V-shaped cross-section." However, this argument is not persuasive. Mault does, in fact, teach a discard breath outlet 72 oriented such that discard breath is not directed into the device ("reusable main portion") 24 or at an operator of the breath testing device ("calorimeter") 10 (Fig. 4 of Mault) during testing when the operator views the display 18 (Col. 4, lines 3-5 of Mault), and wherein the mouthpiece ("disposable flow tube portion") 22 includes a D-shaped cross-section ("shell") 34.

Likewise, the rejection of claims 15 and 16 are maintained for the same reasons as claim 13.

5. Applicant's arguments, see Remarks, pp. 16-21, filed 28 August 2008, with respect to the rejection of claims 23, 24, 26-32, 34, 47, 48, and 50-53 under 35 U.S.C.

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103(a) as being Mault in view of Raemer, have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, p. 17, that “Neither Mault nor Raemer, considered alone or in combination, describes or suggests a breath tester housing assembly as is recited in Claim 23. More specifically, neither Mault nor Raemer, considered alone or in combination, describes nor suggests a breath tester housing assembly that includes a mouthpiece configured to be removably coupled to a mouthpiece interface, and an alcohol sensor in fluid communication with the mouthpiece and mouthpiece interface.” However, this argument is not persuasive. Mault does, in fact, teach a breath tester housing assembly (“calorimeter”) 10 (Figs. 3 and 4 of Mault) that includes a mouthpiece (“disposable flow tube portion”) 22 configured to be removably coupled to a mouthpiece interface (“recess”) 26. Additionally, Raemer does, in fact, teach an alcohol sensor in fluid communication with a mouthpiece (not labeled) 10 and mouthpiece interface (“valve”) 11 (Fig. 1 and Col. 6, lines 54-57, of Raemer). Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant’s invention was made to have modified the metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual. Mault also suggests that other other gas sensors may be included that can measure respiration components of interest (Col. 31, lines 49-63 of Mault).

Likewise, the rejection of claims 24, 26-32, and 34 are maintained for the same reasons as claim 23.

Applicant contends, see Remarks, pp. 18-19, that "Neither Mault nor Raemer, considered alone or in combination, describes or suggests a breath testing device mouthpiece as is recited in Claim 47. More specifically, neither Mault nor Raemer, considered alone or in combination, describes nor suggests a breath testing device mouthpiece that includes a mouthpiece configured to be pivotally coupled in one orientation within a breath testing device interface." However, this argument is not persuasive. Mault does, in fact, breath testing device 320 that includes a mouthpiece 326 configured to be pivotally coupled in one orientation within a breath testing device interface (Figs. 21 and 22 of Mault). Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual. Mault also suggests that other other gas sensors may be included that can measure respiration components of interest (Col. 31, lines 49-63, of Mault).

Likewise, the rejection of claims 48 and 50-53 are maintained for the same reasons as claim 47.

6. Applicant's arguments, see Remarks, pp. 16-21, filed 28 August 2008, with respect to the rejection of claims 36-42, 44, 45, and 61 under 35 U.S.C. 103(a) as being

Mault in view of Raemer, have been fully considered, but are moot in view of the new ground(s) of rejection.

7. Applicant's arguments, see Remarks, pp. 21-23, filed 28 August 2008, with respect to the rejection of claim 25 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 23 above, have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, pp. 18-19, that "None of Mault, Raemer or Sheehan, considered alone or in combination, describes or suggests a breath tester housing assembly as is recited in Claim 23. More specifically, none of Mault, Raemer or Sheehan, considered alone or in combination, describes nor suggests a breath tester housing assembly that includes a mouthpiece configured to be removably coupled to a mouthpiece interface, wherein mouthpiece interface includes a channel sized to receive the mouthpiece therein, and wherein the mouthpiece is configured to pivotally couple within the mouthpiece interface." However, this argument is not persuasive. The features upon which applicant relies (i.e., "a mouthpiece configured to be removably coupled to a mouthpiece interface, wherein mouthpiece interface includes a channel sized to receive the mouthpiece therein, and wherein the mouthpiece is configured to pivotally couple within the mouthpiece interface") are not recited in either the rejected claim 25 or independent claim 23 for which claim 25 depends on.

8. Applicant's arguments, see Remarks, pp. 21-23, filed 28 August 2008, with respect to the rejection of claim 43 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 36 above, have been fully considered, but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments, see Remarks, pp. 23-24, filed 28 August 2008, with respect to the rejection of claim 33 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 23 above, and further in view of Wolf, have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, pp. 23, that "None of Mault, Raemer or Wolf, considered alone or in combination, describes or suggests a breath tester housing assembly as is recited in Claim 23. More specifically, none of Mault, Raemer or Wolf, considered alone or in combination, describes nor suggests a breath tester housing assembly that includes a mouthpiece configured to be removably coupled to a mouthpiece interface." However, this argument is not persuasive. Mault does, in fact, recite a breath testing housing assembly 10 that includes a mouthpiece 20 configured to be removably coupled to a mouthpiece interface ("recess") 26 (Fig. 3 of Mault).

10. Applicant's arguments, see Remarks, pp. 24-25, filed 28 August 2008, with respect to the rejection of claim 35 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 23 above, and further in view of Lutz, have been fully considered, but they are not persuasive for the same reasons as claim 23 above.

11. Applicant's arguments, see Remarks, pp. 24-27, filed 28 August 2008, with respect to the rejection of claim 46 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 36 above, and further in view of Lutz, have been fully considered, but are moot in view of the new ground(s) of rejection.

12. Applicant's arguments, see Remarks, pp. 24-27, filed 28 August 2008, with respect to the rejection of claim 49 under 35 U.S.C. 103(a) as being Mault in view of Raemer, as applied to claim 47 above, and further in view of Lutz, have been fully considered, but they are not persuasive for the same reasons as claim 47 above.

13. Applicant's arguments, see Remarks, pp. 27-28, filed 28 August 2008, with respect to the rejection of claims 54, 55, and 57-60 under 35 U.S.C. 103(a) as being Mault in view of Lutz, have been fully considered, but they are not persuasive.

Applicant contends, see Remarks, p. 16, that "Neither Mault nor Lutz, considered alone or in combination, describes or suggests a mouthpiece for a breath testing device as is recited in Claim 54. More specifically, neither Mault nor Lutz, considered alone or in combination, describes nor suggests a mouthpiece that includes at least one port being for use in channeling discard breath air from the mouthpiece during testing, wherein the port is oriented with respect to the mouthpiece such that discard breath is not directed towards an operator of the breath testing device during testing." However, this argument is not persuasive. Mault does, in fact, teach a mouthpiece 20 that includes at least one port 72 being for use in channeling discard breath air from the mouthpiece 20 during testing, wherein the port 72 is oriented with respect to the mouthpiece

such that discard breath is not directed towards an operator of the breath testing device during testing (Fig. 4 and Col. 4, lines 3-5 of Mault).

Likewise, the rejection of claims 55 and 57-60 are maintained for the same reasons as claim 54.

14. Applicant's arguments, see Remarks, p. 29, filed 28 August 2008, with respect to the rejection of claims 13, 15, 16, 23-27, 47-55, and 57-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 11-29 of U.S. Patent Application No. 11/089,655, have been fully considered. The rejection is withdrawn because U.S. Patent Application No. 11/089,655 has not been abandoned.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 1, 4-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Sheehan, Raemer, and Burroughs, U.S. Patent No. 3,880,591 A ("Burroughs").

In reference to claims 1, 7, 9 and 12:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject, which

comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator, which has a front edge (the same side display 18 of Mault) and an opposite back edge (the same side as mouthpiece 14). The device further comprises a display (18 of Mault) oriented on one of the edges and aligned with an operator's direct line of view while gripping the base (Fig. 1 of Mault). A mouthpiece interface (32 of Mault) is used for interfacing with a removable mouthpiece, wherein the mouthpiece interface is oriented with respect to the base such that when the operator stands in front of the subject and a subject blows into the mouthpiece the display is not in the direct line of view of the subject (Fig. 1 of Mault). An actuator including a manual sample button (16 of Mault) is located on the edge adjacent to the display. The discard breath is not directed at the operator (port G, and 72 of Mault).

However, Mault fails to teach that:

The actuator is located on the edge of the base opposite the display and an alcohol sensor is fluidly connected to the mouthpiece interface. The alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Sheehan teaches:

A portable data collection device for diagnosing and data collection

(Abstract of Sheehan) comprising actuator buttons placed on the same (216 of Sheehan) or opposite (218 of Sheehan) side of the display (220 of Sheehan). The input dials (216 and 218 of Sheehan) control the operation of the device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have placed the operating actuator buttons on the gripping handle of the device, similar to the teachings of Sheehan, in the Calorimeter of Mault, in order to allow the subject more convenience while operating the device.

However, the combination fails to teach that:

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer) which comprises a sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO₂ and O₂ levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art

at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault as modified by Sheehan to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual. However, the combination fails to teach that:

The mouthpiece interface comprises a channel sized to receive the mouthpiece therein, the mouthpiece configured to be pivotally coupled in one orientation within the mouthpiece interface.

Burroughs teaches:

A breath testing device 12 (Figs. 1-3 of Burroughs), comprising: a mouthpiece interface for interfacing with a removable mouthpiece 14, the mouthpiece interface comprising a channel 16 sized to receive the mouthpiece 14 therein, the mouthpiece 14 configured to be pivotally coupled in one orientation within the mouthpiece interface (see Col. 4, lines 12-26, of Burroughs).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to have a mouthpiece interface comprising a channel sized to receive the mouthpiece therein and the mouthpiece configured to be pivotally coupled in one orientation within the mouthpiece interface because Burroughs teaches such a mouthpiece interface design

that could be used with a "wide variety of devices, instruments and systems which are constructed to receive breath expelled by a subject individual and to provide useful information derived from a sample of such breath or from the act of expiring or exhaling" (see Col. 1, lines 4-19, and Col. 3, lines 5-13, of Burroughs).

In reference to claim 4:

The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26 of Mault) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68 of Mault) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault).

In reference to claims 5 and 6:

The mouthpiece interface is oriented with respect to the housing such that the mouthpiece extends outward from the housing back edge when the mouthpiece is coupled to the housing (Fig. 2 of Mault). The mouthpiece extends obliquely from the top surface and substantially parallel to the top surface (Figs. 21 and 24 of Mault).

The mouthpiece of Mault does not extend obliquely from the top surface and as disclosed in Figs. 2 and 4 it extends directly (perpendicular to the top surface) from the top surface of the housing. At the time the applicant's invention was

made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims 5 and 6 because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

In reference to claims 8 and 10:

An actuator (16 of Mault) is used for controlling illumination of a portion of the housing. A light source illuminates at least a portion of the interface, where the housing has an opening for light to pass from an interior of the housing to an exterior of the housing for illuminating at least a portion of the interface (Col. 3, line 59- Col. 4, line 5 of Mault).

16. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Sheehan, Raemer, and Burroughs, as applied to claim 1 above, and further in view of Wolf.

In reference to claim 11:

Mault, as modified by Sheehan and Raemer, teaches all of the claim limitations;
See the rejection of claim 1 above.

However, the combination fails to teach that:

The housing comprises a mouthpiece ejector for facilitating removal of the mouthpiece from the housing.

Wolf teaches:

A hand held device for measuring breath alcohol which comprises an ejector (120 of Wolf) for ejecting the mouthpiece forceably so that the mouthpiece is ejected into a refuse container or onto the ground without the need of the officer administering the test to touch the used mouthpiece (Col. 9, lines 9-17 of Wolf).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have added an ejector, similar to the one taught by Wolf, in the calorimeter level measurement device of Mault, as modified by Sheehan and Raemer, in order to prevent the operator from touching the used mouthpiece after it has been used by the subject.

17. Claims 13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,274,425 to Lutz et al (Hereinafter "Lutz") in view of Mault.

In reference to claims 13 and 15-16:

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a first end (39 of Lutz) and a second end (27 of Lutz). The second end is closed and is rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece further comprises at least one port for channeling air blown into the mouthpiece (through 39 and 15 of Lutz) into the breath testing device. The mouthpiece is made of plastic material (Col. 1, lines 48-50 of Lutz). The mouthpiece snaps into engagement with the breath testing device (snap members 23, 25, 33 and 35 and Col. 3, lines 40-52 of Lutz). A stop member (the bend at 41 of Lutz) extending radially outward from the body to facilitate positioning a subject's mouth during breath testing (Fig. 1 of Lutz).

However, Lutz fails to teach that:

The mouthpiece has a cross-sectional shape being one of: a D-shaped cross-sectional shape and a V-shaped cross-sectional shape.

Mault teaches:

A calorimeter used for measuring the metabolic rate of a subject which comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator (the same side display 18 of Mault). The

housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). A portion of the mouthpiece body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape or a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have replaced the mouthpiece of Lutz with a mouthpiece similar to the one taught by Mault in order to collect breath samples from the subject for further analysis.

Substituting one known element with another would have yielded predictable results. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

18. Claims 23-24, 26-32, 34, 47-48, 50-53, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer.

In reference to claims 23-24 and 29-30:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject which comprises housing (10 of Mault), which comprises a base (12 of Mault), a display (18 of Mault), and a mouthpiece interface (14 or 20 of Mault). The base can be gripped by an operator during testing, and the display is oriented with respect to the housing to be in line with an operator's direct line of view while gripping the base (Fig. 1 of Mault). The mouthpiece is removably coupled to the mouthpiece interface (346 in Fig. 23 and 326 in Fig. 21 of Mault). The mouthpiece comprises at least one substantially planar surface (Fig. 23 of Mault). The mouthpiece interface includes a stop for positively locating the mouthpiece (the ring around the connection 332 of Mault). The mouthpiece is placed against the stop in a

testing position (Fig. 21 of Mault). The housing further comprises at least one actuator for controlling operation of the breath tester (16 of Mault). The mouthpiece is further oriented with respect to the housing such that discard breath discharged from the housing is not directed at the operator (Fig. 4 and output port G, or 72 of Mault).

However, Mault fails to teach that:

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer) which comprises sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO₂ and O₂ levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught

by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

In reference to claims 26-28:

The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault). The mouthpiece interface is further oriented obliquely from the top surface and is substantially parallel to the top surface (Figs. 21 and 23 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). The mouthpiece comprises one of a tube and a funnel (Fig. 23 of Mault). The mouthpiece of Mault does not extend obliquely from the top surface and as disclosed in Figs. 2 and 4 it extends directly (perpendicular to the top surface) from the top surface of the housing. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used

for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

In reference to claims 31-32:

The housing comprises one actuator (16) for controlling illumination of a portion of the housing. A light source is used for illuminating at least a portion of the interface, where an opening on the housing will pass light from an interior to an exterior of the housing (Col. 3, line 59-Col. 4, line 5 of Mault).

In reference to claim 34:

A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section

for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

In reference to claim 47:

Mault teaches a calorimeter for measuring the metabolic rate of a subject, which comprises a mouthpiece (14 or 20 of Mault). The mouthpiece comprises a first end (seal 354 of Mault), a second end (the end attached to 346 of Mault), and a body extending there between (344 of Mault). A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section. The body further comprises a passageway extending through the body from the first end towards the second end (Fig. 24 of Mault), where the passageway channels the air blown into the mouthpiece into the breath testing device (Fig. 4 of Mault).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of

ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claim 47 because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claims 48 and 50-53:

The body further comprises an external surface (the outside surface of 344 of Mault), an internal surface (internal surface of 344 of Mault), and at least one inlet port (30 of Mault) extending there between. The inlet port channels air from the passageway into the breath testing device (Fig. 4 of Mault). The mouthpiece comprises a substantially planar surface (Fig. 24 of Mault). One of the first end and the second end is rounded to facilitate engagement with the breath testing device (the connection 346 of Mault to the second end of the mouthpiece).

19. Claims 36-42, 44, 45, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer and Brown et al, U.S. Patent No. 5,303,575 A ("Brown").

In reference to claims 36-37 and 40-42, and 61:

Mault teaches:

A calorimeter used for measuring the metabolic rate of a subject which comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator, which has a front edge (the same side display 18 of Mault) and an opposite back edge (the same side as mouthpiece 14). The device further comprises a display (18 of Mault) oriented on one of the edges and aligned with an operator's direct line of view while gripping the base (Fig. 1 of Mault). A mouthpiece interface (32 of Mault) is used for interfacing with a removable mouthpiece (326 of Mault), wherein the mouthpiece interface is oriented with respect to the base such that when the operator stands in front of the subject and a subject blows into the mouthpiece the display is not in the direct line of view of the subject (Fig. 1 of Mault). The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs.

3 and 4 of Mault). The mouthpiece interface is further oriented obliquely from the top surface and is substantially parallel to the top surface (Figs. 21 and 23 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). The mouthpiece comprises one of a tube and a funnel (Fig. 23 of Mault).

As to added limitation, Mault teaches that:

The mouthpiece 326 further configured to be pivotally coupled in one orientation within the housing 320 (Figs. 21 and 22 of Mault).

However, Mault teaches that:

The mouthpiece does not extend obliquely from the housing and as disclosed in Figs. 2 and 4 it extends directly perpendicular from the housing.

Brown teaches:

A breath tester assembly 20 comprising a mouthpiece 24 that extends obliquely from a housing 21. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used

for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

However, Mault fails to teach that;

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer), which comprises a sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO₂ and O₂ levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the

metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

In reference to claims 38-39:

The housing comprises one actuator (16) for controlling illumination of a portion of the housing. A light source is used for illuminating at least a portion of the interface, where an opening on the housing will pass light from an interior to an exterior of the housing (Col. 3, line 59-Col. 4, line 5 of Mault).

In reference to claim 44:

A portion of the mouthpiece has a cross-sectional shape that is substantially similar to at least portion of a cross-sectional shape defined by the mouthpiece interface, such that the mouthpiece interface facilitates positioning the mouthpiece in proper alignment with respect to the housing (the inlet port 346 of Mault and the narrower side of the funnel 344 of Mault have the same cross section).

In reference to claim 45:

A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section.

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was

made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

20. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer, as applied to claim 24 above, and further in view of Sheehan; and Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer and Brown, as applied to claim 37 above, and further in view of Sheehan.

In reference to claims 25 and 43:

Mault, as modified by Raemer, or Raemer and Brown, teaches all of the claim limitations; see the rejections of claim 23 and 37 above.

However the combination fails to teach that:

The manual sample button is located on an edge of the housing base that is opposite an edge where the display is located.

Sheehan teaches:

A portable data collection device for diagnosing and data collection (Abstract of Sheehan) comprising actuator buttons placed on the same (216 of Sheehan) or opposite (218 of Sheehan) sides of the display (220 of Sheehan). The input dials (216 and 218 of Sheehan) control the operation of the device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have placed the operating actuator buttons on the gripping handle of the device, similar to the teachings of Sheehan, in the Calorimeter of Mault as modified by Raemer, in order to give the subject more convenience while operating the device.

21. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer as applied to claim 23 above, and further in view of Wolf.

In reference to claim 33:

Mault, as modified by Reamer teaches all of the claim limitations; see the rejection of claim 23 above.

However, the combination fails to teach that:

The housing comprises a mouthpiece ejector for facilitating removal of the mouthpiece from the housing.

Wolf teaches:

A hand held device for measuring breath alcohol which comprises an ejector (120 of Wolf) for ejecting the mouthpiece forcefully, so that the mouthpiece is ejected into a refuse container or onto the ground without the need of the officer administering the test to touch the used mouthpiece (Col. 9, lines 9-17 of Wolf).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have added an ejector, similar to the one taught by Wolf, in the calorimeter level measurement device of Mault as modified by Raemer in order to prevent the operator from touching the used mouthpiece after it has been used by the subject.

22. Claims 35 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer as applied to claims 23 and 47 above, and further in view of Lutz; and Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer and Brown, as applied to claim 37 above, and further in view of Lutz.

In reference to claims 35 and 46:

Mault, as modified by Raemer, or Raemer and Brown, teaches all of the claim limitations; see the rejections of claim 23 and 37 above.

However, the combination fails to teach that:

The first end of the mouthpiece body is closed and an opposed

second end of the body is open to enable a subject being tested to blow air into the body; that the body further comprises at least one port for blown air to pass through the port; and that the first end has a semi-circular cross-sectional profile.

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a second end (39 of Lutz) and a first end (27 of Lutz). The second end is closed and rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece has a substantially semi-circular (the cross-section at 27 of Lutz).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have substituted the mouthpiece of the metabolic calorimeter of Mault with a mouthpiece similar to the one taught by Lutz, in order to test the breath gases of a subject. The substitution of one known element in the art with another would have yielded predictable results.

In reference to claim 49:

Mault, as modified by Raemer, teaches all of the claim limitations; see the rejection of claim 47 above.

The body further comprises an external surface (The outside surface of mouthpiece 5 of Lutz), an internal surface (inside surface of mouthpiece 5 of Lutz), and at least one outlet port (39 and 15 of Lutz) extending there between, where the outlet port channels discard breath air from the mouthpiece during testing.

23. Claim 54-55 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Lutz.

In reference to claims 54-55 and 57-60:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject which comprises a mouthpiece (20 of Mault). The mouthpiece comprises a first end (seal 354 of Mault), a second end (the end attached to 346 of Mault), and a body extending there between (344 of Mault). A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section. The design of the mouthpiece or using an entirely different shape mouthpiece would not change the functionality of the claimed invention. The body further comprises a passageway extending through the body from the first end towards the second end (Fig. 24 of Mault), where the passageway

channels the air blown into the mouthpiece into the breath testing device (Fig. 4 of Mault). The port (72 of Mault) is defined within the second body portion for channeling air blown into the first end into the breath testing device during testing (inlet port 30 of Mault). One of the first end and the second end is rounded to facilitate engagement with the breath testing device (the connection 346 of Mault to the second end of the mouthpiece). One of the first body portion and the second body portion has a substantially semi-circular cross-sectional shape (Fig. 24 of Mault).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such

modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

However, Mault fails to teach that:

One port is defined within the first body portion for channeling discard breath air from the mouthpiece during testing, and it is oriented with respect to the mouthpiece such that discard breath is not directed towards an operator of the breath testing device during testing. The second end of the mouthpiece is closed, while the first end is open to enable a subject being tested to blow air into the mouthpiece.

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a second end (39 of Lutz) and a first end (27 of Lutz). The second end is closed and rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece has a substantially semi-circular (the cross-section at 27 of Lutz). Lutz also discloses that the exhaled air is passed through an opening (15 of Lutz) in order to be analyzed by the alcohol sensors to detect the blood alcohol levels of the user (Fig. 2 and Col. 3, lines 26-53 of Lutz).

It would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have substituted the mouthpiece of the metabolic calorimeter of Mault with a mouthpiece similar to the one taught by Lutz, in order to test the breath gases of a subject. The substitution of one known element in the art with another would have yielded predictable results.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

24. Claims 13, 15-16, 23-27, 47-55 and 57-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-29 of copending Application No. 11/089,655. Although the conflicting

claims are not identical, they are not patentably distinct from each other because both co-pending applications are drawn to a breathalyzer, which comprises housing and a mouthpiece with the same features indicated in claims above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

25. Applicant's amendment, filed on 28 August 2008, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is

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(571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/N. N./
Patent Examiner, Art Unit 3735
12/06/2008